HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

April 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
CIN-WL-01-7174

Zsigmond Kovacs, President
Control-X Medical, Inc.
2289 Westbrooke Drive
Columbus, Ohio 43228

Dear Mr. Kovacs:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on March 23-28, 2001, our Investigator collected information that revealed serious regulatory problems involving diagnostic x-ray equipment such as x-ray generators and radiographic tables which are manufactured and distributed by your firm.

Under the Federal Food, Drug and Cosmetic Act (the Act), diagnostic x-ray equipment such as x-ray generators and radiographic tables are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation (QS Regulation) as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that your devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to establish and document a formal quality assurance program. For example, there is no individual or group identified to perform quality assurance functions. The quality audit procedure does not insure that the individual performing the quality audit is independent and does not have direct responsibility for the matters being audited. There was no documentation to demonstrate that quality audits were conducted in 1999 or 2000.

Failure to establish and maintain procedures for implementing corrective and preventative action. Procedures addressing documentation of corrective and preventive action activities have not been established, defined, documented and implemented.

Failure to establish and implement an adequate complaint handling program. For example, your firm's complaint handling procedure does not describe the process your firm will use to review, evaluate, and when appropriate, investigate complaints. In addition, there is no documentation to show that complaints are reviewed.

Failure to establish and implement adequate record keeping procedures. Procedures have not been established, defined and documented to ensure that device history records for each batch, lot or unit are maintained to demonstrate that your firm's devices are manufactured in accordance with a device master record and Quality Systems regulation. Also, device history records for your firm's devices are incomplete in that they do not include the primary identification label and labeling for each device that you manufacture.

Failure to establish written design control procedures and a design history file. For example, for the latest development plan for the [redacted] Project, there is no established design and development plan that includes defining all elements of the design process to include design inputs, design outputs, design review, design verification, design validation, design transfer, and establishment of a design history file.

Failure to develop, maintain and implement written MDR procedures. There is no procedure in place to ensure that any complaint that represents an event, which must be reported to FDA under the Medical Device Reporting regulation, is promptly reviewed, evaluated, investigated and reported.

Failure to establish adequate procedures for identifying training needs and to ensure that all personnel are trained to adequately perform their assigned responsibilities. You firm has no records showing that training in given to employees. In addition, procedures for identifying training needs have not been established, defined and implemented.

Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. For example, there is no documentation showing that the oscilloscopes used during troubleshooting in manufacturing have been calibrated as required by your firm's e procedure for "Measuring Equipment Inspection Calibration" dated 3/25/98.

Failure to establish and maintain procedures to adequately control environmental conditions in situations where environmental conditions could reasonably be expected to have an adverse effect on product quality. For example, there are no precautions taken for electrostatic discharge while testing, assembling or troubleshooting circuit boards.

Failure to establish and maintain a procedure to control all documents that are required by the Quality System Regulation.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the FDA inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,

Deborah Gorle
for Henry L. Fielden
District Director
Cincinnati District